



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Van der Ploeg et al.

Serial No.: 10/603,249

Case: 20561YDA

Art Unit: 1632

Filed: June 25, 2003

For: MELANOCORTIN-3 RECEPTOR DEFICIENT
CELLS, NON-HUMAN TRANSGENIC ANIMALS
AND METHODS OF SELECTING COMPOUNDS
WHICH REGULATE BODY WEIGHT

Examiner:
Falk, Anne Marie

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

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MERCK & CO., INC.

BY: Danielle J. Maranto

REGISTRATION NO.: 7A

DATE: March 29, 2006

RESPONSE TO RESTRICTION REQUIREMENT, 35 U.S.C. § 121

Dear Sir:

In response to the Restriction Requirement mailed March 2, 2006, please consider the following election. Time for responding to this Restriction Requirement has been calculated to run through April 2, 2006. However, if additional time is required to enter this response, please treat this paper as a request under 37 C.F.R. §1.136(a) to extend the time as required, and charge Deposit Account No. 13-2755 the appropriate fee as a large entity. Please credit any overpayment or charge any fee deficiency to Deposit Account No. 13-2755.

The Examiner has set forth the following restriction requirement under 35 U.S.C. §121:
Group I consisting of claims 30-32 drawn to a transgenic mouse comprising an altered MC-3R gene and further comprising a non-native MC-3R gene.

Group II consisting of claims 36-43 drawn to a transgenic animal having both altered MC-3R and MC-4R genes, as well as cells derived from said animal.

Group III consisting of claims 44-46 drawn to a transgenic mouse having both altered MC-3R and MC-4R genes, and further comprising non-native MC-3R and MC-4R genes.

Group IV consisting of claims 47, 48 and 50-53 drawn to methods for determining if a substance is (a) capable of binding to MC-3R, (b) capable of activating MC-3R and regulating body weight, (c) a potential agonist or antagonist of MC-3R and regulates body weight, and (d) capable of binding to MC-3R and regulating body weight.

Group V consisting of claim 49 drawn to a method of identifying a substance which modulates MC-3R receptor activity and regulates body weight.

Group VI consisting of claims 54-56 drawn to methods of identifying agonists or antagonists of MC-3R which regulate body weight.

Group VII consisting of claim 57 drawn to a method of selecting a compound which shows *in vivo* efficacy for modulation of MC-3R and regulation of body weight.

Applicants provisionally elect Group IV consisting of claims 47, 48 and 50-53, with traverse, for further prosecution in this application.

As a traverse, it is noted that two criteria are required for a proper restriction of claims in the instant application. First, the inventions must be independent or distinct. Second, searching the additional inventions must constitute an undue burden on the Examiner. Applicants assert that neither criterion as specifically applied to Groups IV-VII have been met and respectfully request reconsideration of the requirement for restriction with respect to said groups.

Each of the claims of Groups IV-VI is drawn to a method of determining or identifying if a substance (*i.e.*, test compound) modulates the activity of MC-3R, obviating their designation as distinct inventions. While a test compound can alter MC-3R activity via a direct (*i.e.*, binding to the receptor) or indirect (*i.e.*, acting upon a component of the biological pathway involved in effectuating MC-3R activity), the end result of modulating receptor activity is the same. Applicants further assert that there is not an undue burden in searching and examining the claims of Groups IV-VI in one application because each of the claims includes the presence of the MC-3R, or chimeric version thereof, a test substance, and the measurement of the direct or indirect modulation of the receptor by said substance.

At the very least, Applicants request that Groups IV and V be combined. There is no undue burden to search for a method of identifying a substance which modulates the human MC-3R (SEQ ID NO:4), as recited in claim 49, when a method of identifying a substance which modulates MC-3R (not specific to a particular species) must be searched and considered at the same time.

Applicants, in summary reiterate their election of Group IV with traverse. Applicants, however, respectfully request that the Examiner consider the above arguments and remove the imposed requirement for restriction as applied to Groups IV-VI.

Applicants maintain that all claims are in condition for allowance and a favorable action on the merits is earnestly solicited.

Respectfully submitted,

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